EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion Part I on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 411, 559, 1174, 1184, 1197, 1380, 1409, 1656, 1667, 1670, 1763, 1767, 1806, 1884, 1908, 1997, 2141, 2159, 2243, 2244, 2325, 2331, 2333, 2336, 2652, 2717, 2727, 2752, 2788, 2861, 2870, 2885, 2894, 3077, 3101, 3516, 3595, 3726, 4252, 4288, 4290, 4406, 4509, 4709) pursuant to Article 13(1) of Regulation (EC) No 1924/2006

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SCIENTIFIC OPINION

Scientific Opinion Part I on the substantiation of health claims related to various food(s)/food constituent(s) not supported by pertinent human data (ID 411, 559, 1174, 1184, 1197, 1380, 1409, 1656, 1667, 1670, 1763, 1767, 1806, 1884, 1908, 1997, 2141, 2159, 2243, 2244, 2325, 2331, 2333, 2336, 2652, 2717, 2727, 2752, 2788, 2861, 2870, 2885, 2894, 3077, 3101, 3516, 3595, 3726, 4252, 4288, 4290, 4406, 4509, 4709) pursuant to Article 13(1) of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to provide a scientific opinion on a list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006. This opinion addresses the scientific substantiation of health claims in relation to various food(s)/food constituent(s) not supported by pertinent human data. The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The references provided in relation to the claims evaluated in this opinion included studies which assessed the effects of food(s)/food constituent(s) other than the food(s)/food constituent(s) which are the subject of the claims, and/or investigated health outcomes unrelated to the claimed effects. No

[1] On request from the European Commission, Question No EFSA-Q-2008-1198, EFSA-Q-2008-1346, EFSA-Q-2008-1913, EFSA-Q-2008-1923, EFSA-Q-2008-1936, EFSA-Q-2008-2117, EFSA-Q-2008-2146, EFSA-Q-2008-2392, EFSA-Q-2008-2403, EFSA-Q-2008-2406, EFSA-Q-2008-2496, EFSA-Q-2008-2500, EFSA-Q-2008-2539, EFSA-Q-2008-2617, EFSA-Q-2008-2641, EFSA-Q-2008-2730, EFSA-Q-2008-2874, EFSA-Q-2008-2892, EFSA-Q-2008-2976, EFSA-Q-2008-2977, EFSA-Q-2008-3058, EFSA-Q-2008-3064, EFSA-Q-2008-3066, EFSA-Q-2008-3069, EFSA-Q-2008-3385, EFSA-Q-2008-3450, EFSA-Q-2008-3460, EFSA-Q-2008-3485, EFSA-Q-2008-3521, EFSA-Q-2008-3594, EFSA-Q-2008-3603, EFSA-Q-2008-3618, EFSA-Q-2008-3627, EFSA-Q-2008-3809, EFSA-Q-2008-3833, EFSA-Q-2008-4243, EFSA-Q-2008-4320, EFSA-Q-2008-4448, EFSA-Q-2008-4962, EFSA-Q-2010-00241, EFSA-Q-2010-00243, EFSA-Q-2010-00359, EFSA-Q-2010-00462, EFSA-Q-2010-00662, adopted on 08 April 2011.

[2] Panel members: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Hannu Korhonen, Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Ambroise Martin, Bevan Moseley, Monika Neuhäuser-Berthold, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Stephan Strobel, Inge Tetens, Daniel Tomé, Hendrik van Loveren and Hans Verhagen. Correspondence: nda@efsa.europa.eu

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims for the preparatory work on this Scientific Opinion: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Albert Flynn, Ines Golly, Marina Heinonen, Hannu Korhonen, Martinus Løvik, Ambroise Martin, Hildegard Przyrembel, Seppo Salminen, Yolanda Sanz, Sean (J.J.) Strain, Inge Tetens, Hendrik van Loveren and Hans Verhagen.

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human studies, which investigated the effects of the food(s)/food constituent(s) on appropriate measures of the claimed effects, were provided. The Panel considers that no conclusions can be drawn from any of the references provided for the scientific substantiation of the claims evaluated in this opinion.

On the basis of the data presented, the Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effects evaluated in this opinion.

KEY WORDS

Appetite, satiety, body weight, LDL cholesterol, blood pressure, cardiac function, oxidative damage, bowel function, UV-induced photo-oxidative damage, post-prandial glycaemic responses, venous walls, health claims.

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INFORMATION AS PROVIDED IN THE CONSOLIDATED LIST

The consolidated list of health claims pursuant to Article 13 of Regulation (EC) No 1924/2006[4] submitted by Member States contains main entry claims with corresponding conditions of use and literature for similar health claims. EFSA has screened all health claims contained in the original consolidated list of Article 13 health claims which was received by EFSA in 2008 using six criteria established by the NDA Panel to identify claims for which EFSA considered sufficient information had been provided for evaluation and those for which more information or clarification was needed before evaluation could be carried out[5]. The clarifications which were received by EFSA through the screening process have been included in the consolidated list. This additional information will serve as clarification to the originally provided information. The information provided in the consolidated list for the health claims which are the subject of this opinion is tabulated in Appendix C.

ASSESSMENT

The approach used in the evaluation of Article 13(1) health claims is explained in the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims[6].

In assessing each specific food/health relationship that forms the basis of a health claim the NDA Panel considers the extent to which:

1. the food/constituent is defined and characterised;

2. the claimed effect is defined and is a beneficial physiological effect ("beneficial to human health");

3. a cause and effect relationship is established between the consumption of the food/constituent and the claimed effect (for the target group under the proposed conditions of use).

Substantiation of the claim is dependent on a favourable outcome of the assessment of 1, 2 and 3 above. Thus, a cause and effect relationship is considered not to be established if the outcome of any one of these assessments is unfavourable.

For a claim, each relationship between a food/constituent and a claimed effect is assessed separately and individual assessments are combined, as appropriate, to form coherent opinions.

1. Relevance of the claimed effect to human health

1.1. Increase in appetite after unintentional weight loss leading to an increase in energy intake (ID 411, 2141)

The claimed effects are "appetite (stimulation)" and "appetite/digestion". The Panel assumes that the target population is underweight individuals who wish to increase their energy intake.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the increase in appetite after unintentional weight loss.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.
[5] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), 2011. General guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims. EFSA Journal, 9(4):2135, 24 pp.
[6] See footnote 5

The Panel considers that an increase in appetite after unintentional weight loss leading to an increase in energy intake, if sustained, might be a beneficial physiological effect.

1.2. Increase in satiety leading to a reduction in energy intake (ID 1656, 1884, 2870, 2894, 4252)

The claimed effects are "satiety/weight management/promotion of CCK release and soy foods", "alginate forms a gel in the stomach and promotes an immediate feeling of satiety. It may also trap a portion of HCA. Piperine increases the bioavailability of the un-trapped HCA and enhances satiety", "satiety", and "weight management/satiety". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to an increase in satiety. Satiety is the decrease in the motivation to eat after consumption of food. The effect may persist up to several hours, may reduce energy intake either at the next meal or across the day and, if sustained, may lead to a reduction in body weight.

The Panel considers that an increase in satiety leading to a reduction in energy intake, if sustained, might be a beneficial physiological effect.

1.3. Contribution to the maintenance or achievement of a normal body weight (ID 559, 1380, 1656, 1806, 2243, 2325, 2331, 2333, 2336, 2717, 2727, 2788, 2870, 3726, 4252, 4709)

The claimed effects are "weight control; carbohydrate metabolism and insulin sensitivity", "weight management", "satiety/weight management/promotion of CCK release and soy foods", "weight control", "weight loss management, carbohydrate & lipid metabolism improvement", "weight loss management, acid base balancer", "weight management, thermogenesis", "amincissement", "slimming (cellulitis draining)", and "weight management/satiety". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effects refer to the maintenance or achievement of a normal body weight.

Weight management and weight control can be interpreted as contribution to the maintenance of a normal body weight. In this context, weight loss in overweight individuals without achieving a normal body weight is considered to be a beneficial physiological effect.

The Panel considers that contribution to the maintenance or achievement of a normal body weight is a beneficial physiological effect.

1.4. Maintenance of normal blood LDL-cholesterol concentrations (ID 1763, 2861, 3101, 4406)

The claimed effects are "cardiovascular health", "control of blood lipids", and "blood cholesterol". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the maintenance of normal blood LDL-cholesterol concentrations.

The Panel considers that maintenance of normal blood LDL-cholesterol concentrations is a beneficial physiological effect.

1.5. Maintenance of normal blood pressure (ID 2159)

The claimed effect is "heart health". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the maintenance of normal blood pressure.

Blood pressure is the pressure (force per unit area) exerted by circulating blood on the walls of blood vessels. Elevated blood pressure, by convention above 140 mmHg (systolic) and/or 90 mmHg (diastolic), may compromise the normal arterial and cardiac function.

The Panel considers that maintenance of normal blood pressure is a beneficial physiological effect.

1.6. Maintenance of normal cardiac function (ID 1767, 3595, 4509)

The claimed effects are "cardiovascular health", "excellent source of sulforaphane known to help in the management of heart health", and "help restoration of myocardial tissue". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects relate to the maintenance of normal cardiac function.

The Panel considers that maintenance of normal cardiac function is a beneficial physiological effect.

1.7. Protection of DNA, proteins and lipids from oxidative damage (ID 1174, 1184, 1197, 1667, 1997, 2244, 2652, 3077)

The claimed effects are "heart health vascular health", "cardiovascular system", "maintenance of cardiovascular system", "for cardiovascular health", "antioxidant properties/source of anthocyanins and polyphenols with antioxidant activity", "antioxidant properties", "antioxidant effects", and "immune system, antioxidant properties". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to the protection of cells and molecules from oxidative damage caused by free radicals.

Reactive oxygen species (ROS) including several kinds of radicals are generated in biochemical processes (e.g. respiratory chain) and as a consequence of exposure to exogenous factors (e.g. radiation, pollutants). These reactive intermediates damage biologically relevant molecules such as DNA, proteins and lipids if they are not intercepted by the antioxidant network which includes free radical scavengers such as antioxidant nutrients.

The Panel considers that protection of DNA, proteins and lipids from oxidative damage may be a beneficial physiological effect.

1.8. Changes in bowel function (ID 1409, 2141, 2752, 2885, 3516)

The claimed effects are "D/L-lactic acid - L(+)lactic acid activate the gut motility", "appetite/digestion", "improve digestion/transit", "digestion/intestinal tract", and "digestion". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effects refer to changes in bowel function.

The Panel considers that changes in bowel function such as reduced transit time, more frequent bowel movements, increased faecal bulk, or softer stools may be a beneficial physiological effect, provided that these changes do not result in diarrhoea.

1.9. Protection of lipids in the skin from UV-induced photo-oxidative damage (ID 4288, 4290)

The claimed effect is "antioxidant action". The Panel assumes that the target population is the general population.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the protection of lipids in the skin from UV-induced photo-oxidative damage.

The Panel considers that the protection of lipids in the skin from UV-induced photo-oxidative damage is a beneficial physiological effect.

1.10. Reduction of post-prandial glycaemic responses (ID 559)

The claimed effect is "weight control; carbohydrate metabolism and insulin sensitivity". The Panel assumes that the target population is individuals who wish to reduce their post-prandial glycaemic responses.

In the context of the proposed wordings, the Panel assumes that the claimed effect refers to the reduction of post-prandial glycaemic responses.

Postprandial glycaemia is interpreted as the elevation of blood glucose concentrations after consumption of a food and/or meal. This function is a normal physiological response which varies in magnitude and duration and which may be influenced by the chemical and physical nature of the food or meal consumed, as well as by individual factors (Venn and Green, 2007). Reducing post-prandial glycaemic responses may be beneficial to subjects with, for example, impaired glucose tolerance as long as post-prandial insulinaemic responses are not disproportionally increased. Impaired glucose tolerance is common in the general population of adults.

The Panel considers that reduction of post-prandial glycaemic responses (as long as post-prandial insulinaemic responses are not disproportionally increased) may be a beneficial physiological effect.

1.11. Maintenance of elasticity and strength of the venous walls (ID 1670, 1908)

The claimed effect is "vascular health". The Panel assumes that the target population is the general population.

In the context of the proposed wordings and the clarifications provided by Member States, the Panel assumes that the claimed effect refers to the maintenance of elasticity and strength of the venous walls.

The Panel considers that maintenance of elasticity and strength of the venous walls is a beneficial physiological effect.

2. Scientific substantiation of the claimed effect

2.1. Increase in appetite after unintentional weight loss leading to an increase in energy intake (ID 411, 2141)

The references provided in relation to these claims included textbooks which did not provide any original data for the scientific substantiation of the claims. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effect of the food(s)/food constituent(s) on appetite ratings, energy intake or body weight were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and a sustained increase in appetite after unintentional weight loss leading to an increase in energy intake.

2.2. Increase in satiety leading to a reduction in energy intake (ID 1656, 1884, 2870, 2894, 4252)

The references provided in relation to these claims included narrative reviews on the regulation of appetite, energy intake and body weight which did not provide any original data for the scientific substantiation of the claims, addressed the effects of food(s)/food constituent(s) other than those which are the subject of the claims, and/or investigated health outcomes (e.g. post-prandial blood glucose and insulin responses, body composition) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

Some human intervention studies, which investigated the effect of the food(s)/food constituent(s) on appetite ratings and/or subsequent food intake and/or secretion of hormones with a putative role on the regulation of food intake (e.g. glucagon-like peptide-1, cholecystokinin, ghrelin) following a single meal or over 24 hours, were provided. The Panel notes that none of these studies tested the sustainability of an effect of the food(s)/food constituent(s) on appetite ratings and subsequent energy intake (i.e. effects were tested on a single occasion and no information was provided on the repeated consumption of the food(s)/food constituent(s)). The Panel considers that no conclusions can be drawn from these studies for the scientific substantiation of a claim on a sustained increase in satiety leading to a reduction in energy intake.

No human studies which investigated the effects of the food(s)/food constituent(s) on a sustained increase in satiety leading to a reduction in energy intake were provided in relation to any of the claims evaluated in this section.

A number of animal studies which addressed the effects of the food(s)/food constituent(s) on food intake, body weight, and/or secretion of hormones with a putative role on the regulation of food intake, and a number of animal and *in vitro* studies which addressed the mechanisms by which the food(s)/constituent(s) could exert the claimed effect were also provided. The Panel considers that, in the absence of human studies from which conclusions could be drawn for the scientific substantiation of the claim, the evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on an increase in satiety leading to a reduction in energy intake in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and a sustained increase in satiety leading to a reduction in energy intake.

2.3. Contribution to the maintenance or achievement of a normal body weight (ID 559, 1380, 1656, 1806, 2243, 2325, 2331, 2333, 2336, 2717, 2727, 2788, 2870, 3726, 4252, 4709)

Most of the references provided in relation to these claims were narrative reviews on the potential health effects of different food(s)/food constituent(s) which did not provide any original data for the scientific substantiation of the claims, addressed the effects of food(s)/food constituent(s) other than those which are the subject of the claims, and/or investigated health outcomes (e.g. delayed gastric emptying, appetite ratings and/or subsequent food intake following a single meal or over 24 hours, energy expenditure, post-prandial blood glucose responses, insulin sensitivity and/or long-term blood glucose control, treatment of chronic venous insufficiency, bioavailability of different food constituents, on plasma concentrations of carotenoids, blood lipids and/or lipid metabolism, antioxidant properties and/or oxidative stress) other than body weight. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

For ID 2243 and 2325, summaries of two human intervention studies on the effects of the food constituents on body weight were provided. However, the limited methodological data available in the summaries did not allow a complete scientific evaluation. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

For ID 1656 and 2870, some internal reports identified as proprietary by the company reported on human intervention studies on the effects of the food constituents on body weight. The Panel notes that Regulation (EC) No 1924/2006 does not foresee the protection of proprietary data for health claims under Article 13.1 of the Regulation and therefore considers that these data cannot be used for the scientific substantiation of the claims.

No relevant human studies which investigated the effects of the food(s)/food constituent(s) on changes in body weight were provided in relation to any of the claims evaluated in this section.

A number of animal studies which addressed the effects of some of the food(s)/constituent(s) on body weight, and a number of animal and *in vitro* studies which addressed the mechanisms by which the food(s)/constituent(s) could exert the claimed effect were also provided. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on body weight *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and contribution to the maintenance or achievement of a normal body weight.

2.4. Maintenance of normal blood LDL-cholesterol concentrations (ID 1763, 2861, 3101, 4406)

The references provided in relation to these claims were book chapters and narrative reviews on the potential health effects of different food(s)/food constituent(s) which did not provide any original data for the scientific substantiation of the claims, addressed the effects of food(s)/food constituent(s) other than those which are the subject of the claims, and/or investigated health outcomes (e.g. resistance of LDL particles to peroxidation, liver steatosis, platelet aggregation, incidence of chronic diseases such as ischaemic heart disease, cancer, or asthma) other than blood cholesterol concentrations. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s) on blood LDL-cholesterol concentrations were provided in relation to any of the claims evaluated in this section.

A number of animal studies which addressed the effects of some of the food(s)/food constituent(s) on the blood lipid profile, and a number of animal and *in vitro* studies which addressed the mechanisms by which the food(s)/food constituent(s) could exert the claimed effect were provided (e.g. activity of 3-hydroxy-3-methyl-glutaryl-CoA reductase, acyl CoA:cholesterol tranferases and/or microsomal triglyceride transfer protein in the liver). The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on blood LDL-cholesterol concentrations *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and maintenance of normal blood LDL-cholesterol concentrations.

2.5. Maintenance of normal blood pressure (ID 2159)

One reference on the antioxidant properties of different plant extracts and two reviews which did not address the effects of the food, which is the subject of the claim, on blood pressure were cited in relation to this claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

No human studies, which investigated the effects of the food on blood pressure were provided in relation to the claim evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food which is the subject of the claim evaluated in this section and maintenance of normal blood pressure.

2.6. Maintenance of normal cardiac function (ID 1767, 3595, 4509)

The references provided in relation to these claims were book chapters and narrative reviews on the potential health effects of different food(s)/food constituent(s) which did not provide any original data for the scientific substantiation of the claims, addressed the effects of food(s)/food constituent(s) other than those which are the subject of the claims, and/or investigated health outcomes (e.g. treatment of infections, resistance of LDL particles to peroxidation, liver steatosis, platelet aggregation, incidence of chronic diseases such as ischaemic heart disease, cancer, asthma) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s) on heart function were provided in relation to any of the claims evaluated in this section.

One animal study on a mice model of atherosclerosis was provided. The Panel considers that evidence provided in animal studies is not sufficient to predict the occurrence of an effect of the consumption of the food(s)/food constituent(s) on maintenance of normal cardiac function in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and maintenance of normal cardiac function.

2.7. Protection of DNA, proteins and lipids from oxidative damage (ID 1174, 1184, 1197, 1667, 1997, 2244, 2652, 3077)

Most of the references provided in relation to these claims addressed potential health effects of dietary antioxidants in general, of food(s)/food constituent(s) other than those which are the subject of

the claims, and/or reported on claimed effects other than the protection of body cells and molecules from oxidative damage. The latter included references on the development or progression of acute or chronic diseases (e.g. immune dysfunction/susceptibility to infections, cardiovascular diseases, cancer, and degenerative diseases, among others) presumed to be associated with increased levels of oxidative stress and where oxidative damage to cells or molecules has not been considered as an outcome. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

Some intervention studies in humans which investigated the effects of the food(s)/food constituent(s) on the overall antioxidant capacity of plasma assessed by different methods have been provided. These methods included total reactive antioxidant potential (TRAP), trolox-equivalent antioxidant capacity (TEAC), ferric reducing ability of plasma (FRAP), oxygen radical absorbance capacity (ORAC), and dichlorofluorescein (DCF) fluorescence. The Panel considers that the evidence provided in these studies does not predict the occurrence of an effect of the food(s)/food constituent(s) on the protection of body cells and molecules from oxidative damage (Dalle-Donne et al., 2006; Griffiths et al., 2002; Knasmuller et al., 2008; Mayne, 2003).

A number of intervention studies assessed changes in antioxidant enzymes (e.g. superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPx), haemoxigenase) and compounds (e.g. glutathione (GSH)) belonging to the antioxidant network system, or on HDL-associated paraoxonases (e.g. PON-1). The Panel notes that induction of antioxidant enzymes and HDL-associated paraoxonases provides an indication of response to oxidative stress, but it is not specific (e.g. induction of antioxidant enzymes may also be achieved in response to the pro-oxidant effect of a dietary component) and does not reflect oxidative damage to cells or molecules (Niki, 2009).

Some intervention studies in humans which investigated the effects of the food(s)/ food constituent(s) on markers of lipid peroxidation have been provided. Such markers are thiobarbituric acid-reactive substances (TBARS), malondialdehyde (MDA) and/or oxidation lag time of LDL *ex vivo* and/or autoantibodies against oxidised LDL particles. The Panel considers that both TBARS and MDA, when used alone, are not reliable markers of lipid peroxidation (Griffiths et al., 2002; Knasmuller et al., 2008; Lykkesfeldt, 2007). The Panel also considers that no evidence has been provided to establish that the oxidation lag time of LDL particles *ex vivo* or that autoantibodies against oxidised LDL particles predict the resistance of LDL particles to peroxidation *in vivo* (Griffiths et al., 2002; Lapointe et al., 2006; Verhoye and Langlois, 2009).

No human studies which investigated the effects of the food(s)/food constituent(s) on reliable markers of oxidative damage to body cells or to molecules such as DNA, proteins and lipids were provided in relation to any of the claims evaluated in this section.

A number of *in vitro* studies were provided which addressed the antioxidant properties of different food(s)/food constituent(s), either by testing their capacity to scavenge free radicals under controlled conditions or by testing their capacity to prevent or delay protein, lipid or DNA oxidation in different *in vitro* models. Also, studies were provided on the relationship between the intake of the food(s)/food constituent(s) and the claimed effect by measuring markers of protein, lipid and/or DNA oxidation in animals, either *in vivo* or *ex vivo*. The Panel considers that evidence provided in animal and *in vitro* studies is not sufficient to predict the occurrence of an effect of the food(s)/food constituent(s) consumption on the protection of body cells and molecules from oxidative damage *in vivo* in humans.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and protection of DNA, proteins or lipids from oxidative damage.

2.8. Changes in bowel function (ID 1409, 2141, 2752, 2885, 3516)

The references provided in relation to these claims were textbooks, narrative reviews or monographs which did not provide any original data for the scientific substantiation of the claims, studies which addressed the effects of food(s)/food constituent(s) other than those which are the subject of the claims, and/or investigated health outcomes (e.g. glucose tolerance and lipid metabolism, hydrogen and methane production in the gastro-intestinal tract) unrelated to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

No human studies which investigated the effects of the food(s)/food constituent(s) on measures of bowel function were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and changes in bowel function.

2.9. Protection of lipids in the skin from UV-induced photo-oxidative damage (ID 4288, 4290)

The references provided in relation to these claims were monographs which addressed food(s)/food constituent(s) other than those which are the subject of the claims. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claims.

No human studies which investigated the effects of the food(s)/food constituent(s) on protection of lipids in the skin from UV-induced photo-oxidative damage were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) which are the subject of the claims evaluated in this section and protection of lipids in the skin from UV-induced photo-oxidative damage.

2.10. Reduction of post-prandial glycaemic responses (ID 559)

The references provided in relation to this claim included narrative reviews which did not provide any original data for the scientific substantiation of the claims and studies which assessed the effects of food(s)/food constituent(s) other than the food which is the subject of the claim. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

No human studies which investigated the effects of the food on reduction of post-prandial glycaemic responses were provided in relation to the claim evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food which is the subject of the claim evaluated in this section and reduction of post-prandial glycaemic responses.

2.11. Maintenance of elasticity and strength of the venous walls (ID 1670, 1908)

The references provided in relation to these claims included human intervention and animal studies on the effects of the food constituent(s), either alone or in combination with other substances, on health outcomes (e.g. pharmacokinetics, treatment of chronic venous insufficiency, treatment of retinal venous occlusion, red blood cell aggregability, lipid peroxidation, profibrinolytic activity) unrelated

to the claimed effect. The Panel considers that no conclusions can be drawn from these references for the scientific substantiation of the claim.

No human studies which investigated the effects of the food constituent(s) on maintenance of the elasticity and strength of the venous walls were provided in relation to any of the claims evaluated in this section.

The Panel concludes that a cause and effect relationship has not been established between the consumption of the food constituent(s) which are the subject of the claims evaluated in this section and maintenance of the elasticity and strength of the venous walls.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- A cause and effect relationship has not been established between the consumption of the food(s)/food constituent(s) and the claimed effects evaluated in this opinion.

DOCUMENTATION PROVIDED TO EFSA

Health claims pursuant to Article 13 of Regulation (EC) No 1924/2006 (No: EFSA-Q-2008-1198, EFSA-Q-2008-1346, EFSA-Q-2008-1913, EFSA-Q-2008-1923, EFSA-Q-2008-1936, EFSA-Q-2008-2117, EFSA-Q-2008-2146, EFSA-Q-2008-2392, EFSA-Q-2008-2403, EFSA-Q-2008-2406, EFSA-Q-2008-2496, EFSA-Q-2008-2500, EFSA-Q-2008-2539, EFSA-Q-2008-2617, EFSA-Q-2008-2641, EFSA-Q-2008-2730, EFSA-Q-2008-2874, EFSA-Q-2008-2892, EFSA-Q-2008-2976, EFSA-Q-2008-2977, EFSA-Q-2008-3058, EFSA-Q-2008-3064, EFSA-Q-2008-3066, EFSA-Q-2008-3069, EFSA-Q-2008-3385, EFSA-Q-2008-3450, EFSA-Q-2008-3460, EFSA-Q-2008-3485, EFSA-Q-2008-3521, EFSA-Q-2008-3594, EFSA-Q-2008-3603, EFSA-Q-2008-3618, EFSA-Q-2008-3627, EFSA-Q-2008-3809, EFSA-Q-2008-3833, EFSA-Q-2008-4243, EFSA-Q-2008-4320, EFSA-Q-2008-4448, EFSA-Q-2008-4962, EFSA-Q-2010-00241, EFSA-Q-2010-00243, EFSA-Q-2010-00359, EFSA-Q-2010-00462, EFSA-Q-2010-00662). The scientific substantiation is based on the information provided by the Member States in the consolidated list of Article 13 health claims and references that EFSA has received from Member States or directly from stakeholders.

The full list of supporting references as provided to EFSA is available on: http://www.efsa.europa.eu/panels/nda/claims/article13.htm.

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APPENDICES

APPENDIX A

BACKGROUND AND TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Regulation 1924/2006 on nutrition and health claims made on foods[7] (hereinafter "the Regulation") entered into force on 19th January 2007.

Article 13 of the Regulation foresees that the Commission shall adopt a Community list of permitted health claims other than those referring to the reduction of disease risk and to children's development and health. This Community list shall be adopted through the Regulatory Committee procedure and following consultation of the European Food Safety Authority (EFSA).

Health claims are defined as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health".

In accordance with Article 13 (1) health claims other than those referring to the reduction of disease risk and to children's development and health are health claims describing or referring to:

a) the role of a nutrient or other substance in growth, development and the functions of the body; or

b) psychological and behavioural functions; or

c) without prejudice to Directive 96/8/EC, slimming or weight-control or a reduction in the sense of hunger or an increase in the sense of satiety or to the reduction of the available energy from the diet.

To be included in the Community list of permitted health claims, the claims shall be:

(i) based on generally accepted scientific evidence; and

(ii) well understood by the average consumer.

Member States provided the Commission with lists of claims as referred to in Article 13 (1) by 31 January 2008 accompanied by the conditions applying to them and by references to the relevant scientific justification. These lists have been consolidated into the list which forms the basis for the EFSA consultation in accordance with Article 13 (3).

ISSUES THAT NEED TO BE CONSIDERED

IMPORTANCE AND PERTINENCE OF THE FOOD[8]

Foods are commonly involved in many different functions[9] of the body, and for one single food many health claims may therefore be scientifically true. Therefore, the relative importance of food e.g. nutrients in relation to other nutrients for the expressed beneficial effect should be considered: for functions affected by a large number of dietary factors it should be considered whether a reference to a single food is scientifically pertinent.

[7] OJ L12, 18/01/2007
[8] The term 'food' when used in this Terms of Reference refers to a food constituent, the food or the food category.
[9] The term 'function' when used in this Terms of Reference refers to health claims in Article 13(1)(a), (b) and (c).

It should also be considered if the information on the characteristics of the food contains aspects pertinent to the beneficial effect.

SUBSTANTIATION OF CLAIMS BY GENERALLY ACCEPTABLE SCIENTIFIC EVIDENCE

Scientific substantiation is the main aspect to be taken into account to authorise health claims. Claims should be scientifically substantiated by taking into account the totality of the available scientific data, and by weighing the evidence, and shall demonstrate the extent to which:

(a) the claimed effect of the food is beneficial for human health,

(b) a cause and effect relationship is established between consumption of the food and the claimed effect in humans (such as: the strength, consistency, specificity, dose-response, and biological plausibility of the relationship),

(c) the quantity of the food and pattern of consumption required to obtain the claimed effect could reasonably be achieved as part of a balanced diet,

(d) the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.

EFSA has mentioned in its scientific and technical guidance for the preparation and presentation of the application for authorisation of health claims consistent criteria for the potential sources of scientific data. Such sources may not be available for all health claims. Nevertheless it will be relevant and important that EFSA comments on the availability and quality of such data in order to allow the regulator to judge and make a risk management decision about the acceptability of health claims included in the submitted list.

The scientific evidence about the role of a food on a nutritional or physiological function is not enough to justify the claim. The beneficial effect of the dietary intake has also to be demonstrated. Moreover, the beneficial effect should be significant i.e. satisfactorily demonstrate to beneficially affect identified functions in the body in a way which is relevant to health. Although an appreciation of the beneficial effect in relation to the nutritional status of the European population may be of interest, the presence or absence of the actual need for a nutrient or other substance with nutritional or physiological effect for that population should not, however, condition such considerations.

Different types of effects can be claimed. Claims referring to the maintenance of a function may be distinct from claims referring to the improvement of a function. EFSA may wish to comment whether such different claims comply with the criteria laid down in the Regulation.

WORDING OF HEALTH CLAIMS

Scientific substantiation of health claims is the main aspect on which EFSA's opinion is requested. However, the wording of health claims should also be commented by EFSA in its opinion.

There is potentially a plethora of expressions that may be used to convey the relationship between the food and the function. This may be due to commercial practices, consumer perception and linguistic or cultural differences across the EU. Nevertheless, the wording used to make health claims should be truthful, clear, reliable and useful to the consumer in choosing a healthy diet.

In addition to fulfilling the general principles and conditions of the Regulation laid down in Article 3 and 5, Article 13(1)(a) stipulates that health claims shall describe or refer to "the role of a nutrient or other substance in growth, development and the functions of the body". Therefore, the requirement to

describe or refer to the 'role' of a nutrient or substance in growth, development and the functions of the body should be carefully considered.

The specificity of the wording is very important. Health claims such as "Substance X supports the function of the joints" may not sufficiently do so, whereas a claim such as "Substance X helps maintain the flexibility of the joints" would. In the first example of a claim it is unclear which of the various functions of the joints is described or referred to contrary to the latter example which specifies this by using the word "flexibility".

The clarity of the wording is very important. The guiding principle should be that the description or reference to the role of the nutrient or other substance shall be clear and unambiguous and therefore be specified to the extent possible i.e. descriptive words/ terms which can have multiple meanings should be avoided. To this end, wordings like "strengthens your natural defences" or "contain antioxidants" should be considered as well as "may" or "might" as opposed to words like "contributes", "aids" or "helps".

In addition, for functions affected by a large number of dietary factors it should be considered whether wordings such as "indispensable", "necessary", "essential" and "important" reflects the strength of the scientific evidence.

Similar alternative wordings as mentioned above are used for claims relating to different relationships between the various foods and health. It is not the intention of the regulator to adopt a detailed and rigid list of claims where all possible wordings for the different claims are approved. Therefore, it is not required that EFSA comments on each individual wording for each claim unless the wording is strictly pertinent to a specific claim. It would be appreciated though that EFSA may consider and comment generally on such elements relating to wording to ensure the compliance with the criteria laid down in the Regulation.

In doing so the explanation provided for in recital 16 of the Regulation on the notion of the average consumer should be recalled. In addition, such assessment should take into account the particular perspective and/or knowledge in the target group of the claim, if such is indicated or implied.

TERMS OF REFERENCE

HEALTH CLAIMS OTHER THAN THOSE REFERRING TO THE REDUCTION OF DISEASE RISK AND TO CHILDREN'S DEVELOPMENT AND HEALTH

EFSA should in particular consider, and provide advice on the following aspects:

- Whether adequate information is provided on the characteristics of the food pertinent to the beneficial effect.
- Whether the beneficial effect of the food on the function is substantiated by generally accepted scientific evidence by taking into account the totality of the available scientific data, and by weighing the evidence. In this context EFSA is invited to comment on the nature and quality of the totality of the evidence provided according to consistent criteria.
- The specific importance of the food for the claimed effect. For functions affected by a large number of dietary factors whether a reference to a single food is scientifically pertinent.

In addition, EFSA should consider the claimed effect on the function, and provide advice on the extent to which:

- the claimed effect of the food in the identified function is beneficial.
- a cause and effect relationship has been established between consumption of the food and the claimed effect in humans and whether the magnitude of the effect is related to the quantity

consumed.

- where appropriate, the effect on the function is significant in relation to the quantity of the food proposed to be consumed and if this quantity could reasonably be consumed as part of a balanced diet.
- the specific study group(s) in which the evidence was obtained is representative of the target population for which the claim is intended.
- the wordings used to express the claimed effect reflect the scientific evidence and complies with the criteria laid down in the Regulation.

When considering these elements EFSA should also provide advice, when appropriate:

- on the appropriate application of Article 10 (2) (c) and (d) in the Regulation, which provides for additional labelling requirements addressed to persons who should avoid using the food; and/or warnings for products that are likely to present a health risk if consumed to excess.

APPENDIX B

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation to the marketing of the food/food constituent, a positive assessment of its safety, nor a decision on whether the food/food constituent is, or is not, classified as foodstuffs. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wordings of the claims and the conditions of use as proposed in the Consolidated List may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 13(3) of Regulation (EC) No 1924/2006.

APPENDIX C

Table 1. Main entry health claims related to various food(s)/food constituent(s) that are not supported by pertinent human data, including conditions of use from similar claims, as proposed in the Consolidated List.

ID	Food or Food constituent	Health Relationship	Proposed wording
411	Mineralwasser/ Natriumchlorid. Clarification provided Mineral water/sodium chloride.	Appetit (Anregung). Clarification provided Appetite (stimulation).	[In German:] zur Anregung des Appetits. Clarification provided To stimulate the appetite.
	Conditions of use - ab 200 mg/l Natrium und 200 mg/l Chlorid (siehe EG-Mineralwasser-Richtlinie).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
559	Fructose + dextrose.	Weight control. Carbohydrate metabolism and insulin sensitivity.	Low-calorie and filling snack. Slow carbohydrates prevent rapid changes in blood sugar. Slow carbohydrates help to keep blood sugar levels even for a long time. With no rapid drops in blood sugar people feel more satiated, due to which weight control is easier. Fibre-rich food is good for those wanting to lose weight. Fibre does not contain energy, but is filling.
	Conditions of use - Fruit drink with 3g/100g of carbohydrates, 7.5g/serving, 15g/daily serving, of which sugar 2.2g/100g, 5.5g/serving, 11g/daily serving of which fructose 1.6g/100g, 4,0g/serving, 8.0g/daily serving and dextrose 0.5g/100g, 1.3g/serving, 2.5g/daily serving.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1174	Black rice (Oriza sativa indica), consumed as such, or the bran (pigment fraction) of black rice used as a food ingredient in foods, in particular yoghurts, baked products, food supplements and certain foods for a particular nutritional use.	heart health vascular health	helps keep the heart and arteries healthy #C helps maintain healthy blood cholesterol #B helps protect the body tissue and cells from oxidative damage #A

	Clarification provided Black rice (Oriza sativa indica), consumed as such, or the bran (pigment fraction) of black rice used as a food ingredient in foods, in particular yoghurts, baked products, food supplements and certain foods for a particular nutritional use. Change to anthocyanins, see MS comment		
	Conditions of use - More than 5 g black rice bran per day or the equivalent amount of bran pigment		
	Comments from Member States Information: Black rice (Oryza sativa L. indica) is a special cultivar of the regular rice (i.e. brown rice, which only turns white after the aleuron layer is removed). Its aleuron layer (representing about 6% of total rice grain) has a higher content of anthocyanins and hence has a dark color. SE is therefore of the opinion that since anthocyanins are the active substances of Black rice, item 810 should instead refer to item 1445 anthocyanins, where EFSA comment is 0.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1184	Berries (lingonberry, cloudberry, blueberry, currants, raspberry and strawberry).	Cardiovascular system.	Natural berries contain plenty of natural antioxidants (polyphenolic compounds, Vitamin C and carotenoids) and fibre but only a small amount of energy and sodium. For this reason they are very suitable for a heart-friendly diet.
	Conditions of use - The claim is not linked to the amount of berries used. According to Finnish nutritional recommendations, people should eat plenty of vegetables, berries and fruit, at least five servings per day totalling at least 400 g.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1197	Grape juice.	Maintenance of cardiovascular system.	Grape juice: - plays an important antioxidative function. - helps to maintain a healthy cardiovascular system.
	Conditions of use - 5 - 7,5 ml/kg weight over 7 - 14 days. - At least 50 g per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1380	Apple cider vinegar.	Weight management.	Helps control and normalize body

			weight.
	Conditions of use - Powder: 1,2 g.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1409	Sauerkraut Saft (milchsauer vergorener Weißkohl (Brassica oleracea var. capitata). Clarification provided Sauerkraut juice (lactic acid fermented white cabbage (Brassica loeracea var. capitata).	D/L-Milchsäure - L(+)Milchsäure regt die Darmperistaltik an. Clarification provided D/L-lactic acid - L(+)lactic acid activate the gut motility.	[In German:] Sauerkrautsaft regt die Verdauung an. Clarification provided Helps to support the digestion / contributes to the normal function of intestinal tract / functioning of the stomach / sauerkaut juice activate the eupepsia.
	Conditions of use - Erwachsene, 300 Milliliter (ml), 4 bis 6 Wochen. - 2-3 mal wöchentlich 150 g.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1656	Standardised Potato Extract	Satiety/Weight management/Promotion of CCK release and soy foods.	When taken before a meal, supports the body's natural satiety response naturally supports feelings of fullness after a meal helps manage appetite and hunger promotes feelings of fullness and satiety satiety aid helps to feel full sooner
	Conditions of use - Product-specific claim. 15-30 mg of proteinase inhibitors from the standardized potato extract ingredient, taken one hour before the meal, daily		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1667	Tomato extract, grape seeds extract, vitamin C and E, Selenium (Seresis Pharmaton)	For cardiovascular health Clarification provided Maintenance of heart and cardiovascular health: Helps to protect from environmental stress acting as an antioxidant	For maintenance of heart and cardiovascular health, Helps to improve cardiovascular system, general ageing process, immunological problems and protecting from environmental stresses
	Conditions of use - Target groups: Adults. Applicable to products which contain following daily dosage ranges: Vitamin C: 60-120 mg, Selenium: 25-50 mcg, Vitamin E: 6.7-13.4 mg, Beta-carotene: 2.4-4.8 mg, Tomato extract standardized to 5% lycopene (25-50 mg / day), Grape seed extract standardized 8.5 - 13.0% proanthocyanidins (25-50 mg / day)		

ID	Food or Food constituent	Health Relationship	Proposed wording
1670	Troxerutin	Vascular health. Clarification provided Vascular health. Increases elasticity and strengh of blood vessels and vein walls (flow rate, distension, tonus). Helps improve endothelial function.	Contributes to the normal functioning of the veins.
	Conditions of use - 60 mg/day. - 1mg Rutin.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1763	Hesperidin (a component of citrus peel extract and precursor of hesperitin) (ingredient not found in the spanish food laws).	Cardiovascular health.	Helps maintain normal blood cholesterol levels/Supports heart health (to be evaluated by EFSA).
	Conditions of use - ≥ 400 mg/d.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1767	Antler.	Cardiovascular health.	1. For cardiovascular health. 2. Improves function of the heart.
	Conditions of use - 0,4 g		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1806	Flavonoids from green tea, apple and onion	Weight control	Flavonoids, especially catechins from green tea, reduce the absorption of carbohydrates by 25%. Carbohydrates account for 49% of total energy. Thus the weight slimming effect is a total of 12%. Reduces visceral fat
	Conditions of use - Capsules with flavonoids from green tea (ECGC, epigallocatechin gallate), apple and onion (chemferol, myricetin, quercetin). According to the respondent, the "minimum effect/day" for synergic flavonoids is 25mg, and one capsule is enough to exceed the minimum. The positive effects of flavonoids increase to a certain level as the dose increases, but the effects do not accumulate. - Flavonoids: At least a daily flavonoids intake of 130 mg		

ID	Food or Food constituent	Health Relationship	Proposed wording
1884	Name of Food product: Product-specific claim: sodium alginate, HCA and piperine. Description of food in terms of food legislation categories: food not covered by specific food legislation. Was food on Irish market before 1st July 2007: No	Health benefits of food: Alginate forms a gel in the stomach and promotes an immediate feeling of satiety. It may also trap a portion of HCA. Piperine increases the bioavailability of the un-trapped HCA and enhances satiety. Do benefits relate to a disease risk factor: No. Target group: Adults aged 18 years and over with some exceptions. If exceptions describe: Pregnant, lactating women and children. Also those with calcium deficiency or brittle bones. Reasons for excluding these groups: HCA can influence the body's own production of cholesterol and therefore it may influence indirectly the production of sterols. Pregnancy is a time of extreme sensitivity to steroid hormones so HCA should be avoided and also during lactation. Sodium alginate may decrease the absorption of calcium if taken concomitantly therefore it should be avoided by pregnant, lactating women, children and those with brittle bones or calcium deficiencies.	Exact wording of claim as it appears on product: Helps manage appetite and hunger. Examples of any alternative wording that may be used in relation to claim: Contributes to reduce the appetite/Can help in the management of weight control/Promotes the feeling of fullness and satiety/Helps to fel full sooner/Helps to stay full longer/Assists weight management/Helps to reduce the appetite and inhibits conversion of carbohydrates to fats/Helps maintain a healthy level of appetite. Is claim a picture: No.
	Conditions of use - Number of nutrients/other substances that are essential to claimed effect: 3. Names of nutrient/other substances and Quantity in Average daily serving: 2.20 grams sodium alginate, 1500.00 miligrams HCA, 10 miligrams Piperine. Weight of average daily food serving: 150 mililitre(s). Daily amount to be consumed to produce claimed effect: 300 mililitre(s). Number of food portions this equates to in everyday food portions: 1. Are there factors that could interfere with bioavailability: Yes. Please give reason: Sodium alginate forms a gel when it interacts with gastric acid in the stomach. Sodium alginate my trap a portion of HCA in the gel thus reducing its efficacy. Piperine (black pepper extract), a bioavailability enhancer, acts to increase the un-trapped portion of HCA thus allowing it to		

	carry out its physiological function. Sodium alginate may also interfere with calcium in the body and it is therefore recommended not to take calcium supplements (or any supplements) concomitantly. Length of time after consumption for claimed effect to become apparent: It is apparent immediately. Is there a limit to the amount of food which should be consumed in order to avoid adverse health effects: Don't Know. Where applicable outline nutritional composition (g per 100g) of food: Total Fat: .01, Saturated Fat: .00, Trans Fat: .00, Sugar: .31, Salt: .00, Sodium: .10. Other conditions for use: This beverage should be consumed as part of a varied, balanced and healthy lifestyle. Two beverages are to be consumed daily in order to gain benefit of satiety and no more than 3 beverages are to be consumed daily. The entire beverage must be consumed. This product should be avoided by pregnant and lactating women, children and those with calcium deficiencies or brittle bones.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1908	Diosmin (a component of citrus peel extract and precursor of diosmetin)	Vascular health <u>Clarification provided</u> Vascular health Helps maintain normal blood circulation in the legs. Helps manage inflammatory reactions of the veins. Helps maintain the normal elasticity and integrity of the veins.	Helps maintain a good venous blood circulation. Supports a normal venous function. Helps maintain healthy venous circulation in the legs. Protects veins from inflammatory reactions. Supports the strength of blood vessels.
	Conditions of use - 0.5 - 1.0 g/d		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
1997	Aronia melanocarpa (Common Name : Chokeberry).	Antioxidant properties/source of anthocyanins and polyphenols with antioxidant activity.	Contains antioxidant/s. Is a source of antioxdiant/s. With antioxidant/s. Natural source of beneficial bioactive compounds: polyphenols (anthocyanins, flavonols, tannins), that help maintain optimum antioxidant status of the body.
	Conditions of use - Schulkinder, Erwachsene - 1500Gramm (g) getrocknete Beeren. - Frucht / Äquivalent zumAnthocyanin - Gehalt von 9-15 g frischer Früchte; täglich (45 – 60 mg Anthocyanine ber. als Cyanidin-3-0-galactosid pro Tag). - Fruit / The equivalence of anthocyanins content of 9-15 g of fresh fruits per day (45 – 60 mg anthocyanins calculated as cyanidin-3-0 galactoside per day).		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2141	Sinapis alba (Common Name: White mustard).	Appetite/Digestion.	Contributes to appetite / helps to support the digestion / helps to support the digestive juice flow / contributes to the gastro-intestinal

			movement.
	Conditions of use - Semen (nasienie gorczycy białej) / 15 g na dzień. - Samen / 15 g pro Tag.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2159	Vitis vinifera (Common Name: Grape).	Heart health.	Contributes to a healthy blood pressure.
	Conditions of use - Früchte, Blätter, Samen / Üblicher Verzehr als traditionelles Lebensmittel im Rahmen einer ausgewogenen Ernährung / Äquivalent von 5 g Blättern pro Tag. - Owoc, liście, nasiona / zwykle konsumowane jako tradycyjny artykuł żywnościowy w normalnej diecie / równowartość 5g liścia na dzień. - Fruit, leaf, seed / Usual consumption as traditional foodstuff in a normal diet / The equivalent of 5 g of leaf per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2243	Citrullus lunatus (Watermelon) extract - ACTI-08.	Weight loss management carbohydrate & lipid metabolism improvement.	Helps to improve carbohydrate and fat metabolism of the body Used to facilitate the weight loss Helps to loose weight Contributes to loose weight Used to facilitate the weight loss Helps in weight control Contributes to body weight management.
	Conditions of use - 250 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2244	Citrullus lunatus (Watermelon) extract - ACTI-08.	Antioxidant properties.	Good source of antioxidants Contains naturally occuring antioxidants Has antioxidant properties Acts as an antioxidants Contributes to the protection against oxidation Helps increase the antioxidative capacity of the body Helps preventing oxidation Antioxidants help protect you from free radicals

			Antioxidants help protect your cells and tissues from oxidation Antioxidants contribute to the total antioxidant capacity of the body Antioxidants help to protect your body by reinforcing the body's natural defence against the effects of free radicals
	Conditions of use - 250 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2325	Prunus mume (Plum) extract - INP-08.	Weight loss management Acid base balancer.	Helps to balance the acidity of the body Helps to promote the acide-base balance of the body Helps to the detoxification of the body Used to facilitate the weight loss Helps to loose weight Contributes to loose weight Used to facilitate the weight loss Helps in weight control Contributes to body weight management
	Conditions of use - 350 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2331	Ribes nigrum - nom commun: blackcurrant.	Control of weight.	"Used to facilitate the weight loss in addition to dietetic measures" "Helps to loose weight in addition to dietetic measures" "Contributes to loose weight in addition to dietetic measures" "Helps to maintain the weight" "Contributes to maintain the weight" "Helps in weight control"
	Conditions of use - Traditional use of the leaf / 2-4 g of leaves as an infusion one cup several times daily / Equivalent quantity in extract.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2333	Rice vinegar extract -	Weight loss management	Helps to balance the acidity of the

	INRV-08.	Acid base balancer.	body Helps to promote the acide-base balance of the body Helps to the detoxification of the body Used to facilitate the weight loss Helps to loose weight Contributes to loose weight Used to facilitate the weight loss Helps in weight control Contributes to body weight management
	Conditions of use - 350 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2336	Rubus idaeas (Raspberry) extract - BERI-08.	Weight loss management Thermogenesis.	Helps to enhance the thermogenesis production, wich in turn helps weight control Helps to control the appetit Naturally supports feeling of fullness after a meal Helps to manage appetit and hunger Helps to loose weight Contributes to loose weight Used to facilitate the weight loss Helps in weight control Contributes to body weight management
	Conditions of use - 300 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2652	Extract from Aronia melanocarpa	antioxidant effects	helps to protect cells from the fee-radical damage by oxidative stress
	Conditions of use - at least 1,5g/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2717	Ribes nigrum - nom commun : blackcurrant	Control of weight	"Traditionally used to facilitate the weight loss in addition to dietetic measures" "Used to facilitate the weight loss in

			addition to dietetic measures" "Helps to loose weight in addition to dietetic measures" "Contributes to loose weight in addition to dietetic measures" "Helps to maintain the weight" "Contributes to maintain the weight" "Helps in weight control"
	Conditions of use - Traditional use of the leaf / 2-4 g of leaves as an infusion one cup several times daily / Equivalent quantity in extract - Leaf. Usual consumption as traditional foodstuff in a normal diet		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2727	Grape (Vitis vinifera L)	Weight control	Helps to support in weight loss programs. Helps to support slimming. Helps silhouette to become more refined. Useful in weight loss management.
	Conditions of use - 1200 mg of grape marc powder / day - Fruit. At least 60 mg grape extract per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2752	Radis noir: Raphanus niger (Black radish)	Improve digestion/transit	Usually recognized for helping digestion. Usually recognized for helping transit
	Conditions of use - Traditional use of root: raw or 20 to 50g per day of fresh extract juice		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2788	Zea mays L. ; Common name : Maïs	amincissement	Facilite la perte de poids en complément de mesures diététiques. Help weight loss in addition to dieting
	Conditions of use - Partie : Style ; DJR :400 mg		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2861	Mangosteen (Garcinia mangostana L) fruits and	Control of blood lipids	Mangosteen whole fruit juice/concentrate [contains xanthones

	extracts derived from the fruits		which] may help to regulate blood lipids
	Conditions of use - Typical adult dosage: 30-100 ml daily of whole fruit juice.		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2870	Standardisierter Kartoffelextrakt Clarification provided standardized potatoe extract	Sättigung/ Gewichtsmanagement / Förderung der CCK-Ausschüttung Clarification provided satiation/weight management/promotion of CCK-discharge	[In german :] hilft Ihnen, kontrolliert und nicht zwischen den Mahlzeiten zu essen Clarification provided helps not to eat between meals
	Conditions of use - Other condition: produktspezifische Auslobung. 15-30 mg Proteinasehemmer aus standard. Kartoffelextrakt, täglich 1 Stunde vor jeder Mahlzeit zu nehmen - Other condition: Produktspezifische Angabe: 15-30 mg Proteasehemmer aus standardisiertem Kartoffelextrakt eine Stunde vor den beiden größten Mahlzeiten täglich		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2885	Natural mineral water: Sulphates as Mg-, Na-salts: MgSO4, Na2SO4	Digestion/Intestinal tract	Sulphates promote emptying of bowel.
	Conditions of use - 15% RDA per 100 ml		
	Comments from Member States MS clarification to CoU: 'min. 1200 mg SO42- /L, 300 mL to 1500 mL per day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
2894	Potato protein isolate	satiety	Increases the sense of satiety Elicit satiety Reduces appetite Supports weight control
	Conditions of use - Active component are potato protease inhibitors (PI) in pasteurized potato protein fractions isolated from potato tubers. The amount (w) to elicit its effect depends on the inhibitor activity (IA) of the protein isolate: 0.4 - 2 gram potato protein isolate (for explanation see Solanic document NP07104). PI can be provided by dairy, beverages, soups, meals or meal components. Pregnant women and people including children with a healthy bodyweight are advised to avoid food products which are intended to reduce caloric intake.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3077	Beta carota (carrot juice, lactic acid fermented)	Immunesystem, antioxidantproperties	Supports the immune system, supports the natural antioxidant

		Clarification provided Strengthens the body's naturel defense through antioxidantproperties	system in the body
	Conditions of use - At least 1 glass (= 150 ml) lactic acid fermented carrot juice per day		
	Comments from Member States Additionally the example of wording is modified as follows:Strengthens the body's natural defense. Helps maintain the immune system, the body's natural defenses. Contains a high amount of naturally occurring antioxidants		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3101	Fat-reduced cream powder [rich source of milk sphingomyelin (a sphingolipid)]	Cardiovascular health Clarification provided Cardiovascular health Contributes to heart health and artery health by helping maintain normal blood cholesterol levels. Helps reduce cholesterol levels in people with elevated blood cholesterol.	Helps control blood cholesterol; for people with elevated blood cholesterol
	Conditions of use - ≥0.7g milk sphingomyelin, corresponding to 13.5g fat-reduced cream powder, per eating occasion		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3516	Plante : Pomme Malus communis (=syn. Pirus malus) (Apple) Clarification provided Apple - Malus communis (=syn. Pirus malus)	Digestion Clarification provided Digestion = increase the consistency of stools	Reconnu pour faciliter la digestion/Reconnu pour contribuer à un confort digestif/reconnu pour favoriser le transit par un effet de lest Clarification provided Traditionally used to facilitate the digestion / traditionally used to contribute to the digestive comfort / traditionally used to facilitate a good digestion / traditionally used to enhance le digestion by an effect of load
	Conditions of use - Fruit/ Consommation traditionnelle dans le cadre d'une alimentation normale/l'équivalent de 1g par jour		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3595	SproutGarden® Sprout Blend	Excellent source of sulforaphane known to	SproutGarden® is an excellent source of sulforaphane, a compound

		help in the management of heart health	that has been associated with the maintenance of cardiovascular health.
	Conditions of use - 1-5 grams per dose		
	No clarification provided by Member States		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
3726	(Ananas sativus) obtained from fruit juice and stems AND Dry aqueous extract of pineapple standardized at 2% of bromelain	slimming (cellulitis draining)	Recommended during slimming diet, at the same time of dietary measures. Pineapple is a tropical plant whose stems contain bromelain, a proteolytic enzymatic complex. Bromelain is a proteolytic enzyme with anti-edematous activity which can help to drain tissues with cellulitis.
	Conditions of use - 1160 mg of pineapple powder AND 96 mg of dry aqueous extract of pineapple		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4252	Glycomacropeptide	Weight management/satiety	Recognized for hunger feeling reduction
	Conditions of use - 112 mg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4288	Beta-carotene, vitamine C, vitamine E et sélénium	antioxydant action	Protect fatty acids of skin cell membranes from oxidation after sun exposure
	Conditions of use - 100% RDAs		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4290	Vitamine E and Sélénium	antioxydant action	protect fatty acids of skin cell membranes from oxidation after sun exposure
	Conditions of use - Vitamin E:100%RDAs. Selenium:50µg/day		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4406	Ganoderma lucidum-Mashroom-Reishi mushroom	Blood Cholesterol	Helps to decrease the cholesterol level
	Conditions of use - 150 – 350 mg a day		

ID	Food or Food constituent	Health Relationship	Proposed wording
4509	Zea mays-Radicles-Maize, Cornsilk	help restoration of myocardial tissue	Helps to structure and function of heart
	Conditions of use - Radicles / Usual consumption as traditional foodstuff in a normal diet./ The equivalent of 135 - 180 mg per day.		
ID	**Food or Food constituent**	**Health Relationship**	**Proposed wording**
4709	Fructose, L/Carnitine	Weight Control	instant drink which helps burning fats / accelerate the fats metabolism / increase physical performances and effort resistance
	Conditions of use - 2 envelopes daily / Not for diabetics.		

GLOSSARY AND ABBREVIATIONS

CAT	Catalase
DNA	Deoxyribonucleic acid
DCF	Dichlorofluorescein
FRAP	Ferric reducing ability of plasma
GPx	Glutathione peroxidase
GSH	Glutathione
HDL	High-density lipoproteins
LDL	Low-density lipoproteins
MDA	Malondialdehyde
ORAC	Oxygen radical absorbance capacity
PON	Paraoxonase
ROS	Reactive oxygen species
SOD	Superoxide dismutase
TBARS	Thiobarbituric acid-reactive substances
TEAC	Trolox-equivalent antioxidant capacity
TRAP	Total reactive antioxidant potential
UV	Ultra-violet